1. **Scope**

The Human Research Ethics Procedure outlines the processes associated with human research ethics review and applies to all Torrens University Australia (the University) staff and students who conduct human research under the auspices of the University. It also applies to the University’s Human Research Ethics Committee (HREC) and all staff involved in the ethical review of proposed research.

Human research ethics review is guided by the principles in the:

- National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (the National Statement)
- Australian Code for the Responsible Conduct of Research, 2018
- The University’s Responsible Research Conduct Policy

State and Commonwealth Privacy Legislation may be relevant and University policies also impact on the conduct of research.

2. **Definition of research and human research**

Research is the creation of new knowledge and/or the use of existing knowledge in new and creative ways to generate new concepts, methodologies and understandings.

Human research is any research activity with or about human participants, including their data or tissue. This includes, but is not limited to the following activities:

- surveys, even when participants can respond anonymously,
- observation of humans, including observation of public behaviour,
- interviews,
- focus groups,
- behavioural tests,
- action research,
- exercise testing,
- clinical research and clinical trials.

3. **Human Research Ethics Committee**

The University’s HREC has overall responsibility for ensuring that research involving humans is conducted ethically and that the welfare and rights of participants in research are protected. The Committee assesses applications using the National Statement on Ethical Conduct in Human Research (2007 updated in 2018) as the standard for evaluating applications.

The University’s HREC reviews negligible and low risk projects, as well as high risk projects.
4. Evaluation of risk

It is the researchers’ responsibility to determine the ethical review requirements, and risk category, for their intended project(s), noting that changes to the project may result in changes to ethical review requirements i.e. a previously exempted project may need ethical review for work going forward. Researchers should carefully consider plans for reporting of results as there are cases when the activity will have been expected to have received ethics clearance i.e. some journals will not publish unless ethical review has been undertaken.

4.1 Negligible/low-risk research

The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Examples of inconvenience include:

- filling in a form,
- participating in a survey, or
- giving up time to participate in a research activity.

The expression ‘low-risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.

Examples of discomfort include:

- minor side-effects of medication,
- the discomforts related to measuring blood pressure,
- anxiety induced by an interview.

The following research activities are considered low risk research:

- surveys where the research topic is not controversial and questions are of a non-personal nature and will not (or have the potential to) induce distress or cause reputational or professional harms,
- secondary use of identifiable data or biospecimens where consent at the time of collection was obtained to access, share and use the data for secondary research purposes,
- secondary use of identifiable data where a waiver is requested to access data that does not include personal, medical or health information,
- interviews or Focus Groups where the research topic is not controversial and guiding questions are of a non-personal nature and will not (or have the potential to) induce distress or cause reputational or professional harms,
- research involving participants undergoing a non-clinical intervention/assessment task (e.g. activity) where the research tasks may induce discomfort but will not (or will not have the potential to) induce distress, cause reputational or professional harms, and/or involve an element of active concealment or planned deception.

4.2 Research that is more than low-risk

High-risk research is research in which there is any possibility of harms greater than discomfort, or research which is ineligible for low or negligible risk review (National Statement on Ethical Conduct in Human Research, 2007, Chapter 2.1).

Potential harms in research may include:

- **Physical harms:** including injury, illness, pain
• **Psychological harms**: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease

• **Devaluation of personal worth**: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly

• **Social harms**: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status

• **Economic harms**: including the imposition of direct or indirect costs on participants

• **Legal harms**: including discovery and prosecution of criminal conduct

Research projects that include the following are examples of research that is more than low-risk:

• active concealment or planned deception of participants,

• exposure of illegal activity; and

• research specifically targeting Aboriginal and/or Torres Strait Islander peoples.

In addition, research projects that include any of the following are more than low risk, except where the research uses collections of nonidentifiable data and involves only negligible risk:

• human genetics,

• human stem cells,

• women who are pregnant and the human foetus,

• people who are highly dependent on medical care who may be unable to give consent,

• people with cognitive impairment,

• people with an intellectual disability or a mental illness, and

• people who may be involved in illegal activities.

5. **Ethical review pathways**

Researchers are strongly advised to discuss their proposed study with the Research Office before completing an application form. For complex projects that involve multiple stages, researchers are encouraged to carefully consider how to best present the project to the HREC. In some cases, more than one application may be necessary. The HREC may request that the researcher develop a flowchart to depict the overall study to assist the HREC to better understand the full extent of the research activities.

While all projects, regardless of risk, require HREC review, negligible and low-risk projects may, at the discretion of the Committee, be dealt with through an expedited resubmission process should the application not receive approval in the first instance. This may mean that following initial review from the HREC at a meeting, the Research Office may have delegated authority to handle and approve any required revisions.

6. **Evaluation about whether a project requires ethical review**

6.1 **Research which is exempt from review**

If the research is exempt, it does not need to be submitted for ethical review. The activities, however, must comply with relevant University and national ethical standards and the activity may still require other types of approvals.

The National Statement on Ethical Conduct in Human Research (paragraphs 5.1.22 and 5.1.23) defines research that can be exempted from ethics review as negligible risk research that involves the use of
existing collections of data or records that contain only non-identifiable data about human beings (NHRMC, 2018).

Following are examples of types of research exempt from ethics review:

- systematic reviews and meta-analysis of published and non-identifiable data
- studies that involve data available in the public domain
- experimental or laboratory studies that do not involve data collected from or about humans or animals

Non-research activities exempt from ethics review include quality assurance activities and the publication of case reports. Individual consent should be obtained for the publication of case reports.

For formal recognition of ethics exemption, researchers can submit an ethics exemption request, which will be considered by the HREC. If it is decided that the activity is not suitable for exemption, a full application will need to be made.

6.2 Application for a waiver of consent

The HREC has the authority to apply an exemption in relation to a waiver of consent for the use of personal information in research under privacy legislation. The HREC requires a full ethics application to be made to determine if it is able to do this.

7. Submission of applications for ethical review

All members of a research team have shared responsibility for the ethical conduct of research, and must be aware of and satisfied with the degree to which the conduct of the research meets national requirements and university policy.

Ethics approval cannot be given retrospectively. Once the activity has commenced, it is not possible to receive retrospective ethical review and approval for that project.

Human research activities must not commence until written ethics approval has been granted. Furthermore, a project may require other internal and external approvals prior to commencement (i.e. safety or risk assessment or gatekeeper approval).

Ethics applications can be submitted at any time. Researchers are advised not to wait until the respective meeting submission deadline to submit an application as the Research Office undertakes a screening process before an application is assigned to a meeting.

The HREC uses Ethical Review Manager (ERM) to administer the ethical review process. The ERM can be accessed at https://torrens.forms.ethicalreviewmanager.com/

Researchers are:

- required to submit all new applications, regardless of risk, and all post approval information, such as amendments, annual reports, via an online ERM account. New accounts in ERM can be made by registering via the ‘New User’ tab.
- to ensure all other documents relevant to the project are also submitted, including evidence of approval from the relevant Academic Unit. Failure to do this will result in delay and incomplete submissions will not be accepted.
8. Torrens University Australia specific requirements

8.1 Collection of survey data

The University has a Qualtrics license to support researchers and Higher Degree by Research students to collect survey data for research purposes. The use of other survey tools is generally not accepted, unless there are exceptional circumstances. Questions regarding Qualtrics access, accounts and usage should be directed to IT Services.

8.2 Students as potential participants

Academic staff should note that access to student records for teaching purposes does not grant access for research purposes. Projects that wish to use student data from the student’s academic record for research purposes will require an ethics application.

8.3 Undergraduate and Masters Coursework students collecting and using data about others

Undergraduate and Masters coursework student activities conducted only for the purposes of assessment and not resulting in any publication/dissemination do not require ethical review. The Assessment Policy for Higher Education Coursework and ELICOS governs such activities. Whether or not a formal ethical approval process is required, the human ethics values of merit and integrity, justice, beneficence and respect should be considered in the design of such projects. These activities require that participants are informed that ethical approval has not been secured, but that approval by the relevant academic unit has been granted. Participants must be informed that the activity is a learning exercise.

The results of such projects cannot be disseminated in a public arena or via research publication. Note that if the output has received funding or can be counted as part of “Excellence in Research Australia” reporting, then it is considered research and will need ethical review. Official HREC forms or documents are not to be used in association with these assessment exercises. If researchers intend to publish work from research designed and completed as an assessment exercise in a public arena (e.g. an academic or scholarly journal, a paper or presentation at a research conference), ethical review is required.

Coursework Masters students should discuss with an academic staff member to determine if their activity requires ethical approval.

8.4 Other learning and teaching activities

Other learning and teaching contexts where formal human research ethics approval is not required include:

- practitioner research on an intervention or other aspect of teaching and learning that would be normal practice in a school or educational or professional context (if there is no intention to publish). Professional practice/consultation is covered by the codes of ethics and practice of the relevant professional association and does not require human research ethics approval unless the activity is also part of an experiment using human participant(s). Where a student is involved in a professional practice program involving human participants (e.g. external work experience), the supervisor must take full responsibility for the observance, by the student, of those codes. The student must be provided with details of the relevant professional codes of ethics and practice and the supervisor should ensure that the student is familiar with their requirements, including legal requirements such as privacy legislation, before undertaking the activity.

- reflexive qualitative research where the primary data source is the researcher, rather than other people e.g. journal entries, auto ethnographies or self-study, some narrative research, some other arts-based research.

- primary data that is already in the public domain e.g. literature-based research, research into popular culture, policy and other government documents.
8.5 Academics conducting quality assurance and evaluation activities

The NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities is designed to assist in determining whether an activity can be classed as Quality Assurance (QA) or an evaluation activity. Researchers are advised to review section 2(e) “[t]riggers for consideration of ethical review” when determining if their activity may be exempt. Researchers should note that, even if the activity can be classified as QA or evaluation, the activity must be conducted in a way that meets the ethics principles in the National Statement.

If the activity is for quality assurance or improvement of teaching, and is not research, it can be exempt from review. Evaluations of teaching and learning involve many of the same activities as conducting research. Such evaluations are treated as research only when the results will be published or disseminated outside Torrens University Australia.

8.6 Approval from the Academic Unit

All ethics submissions must be supported by a letter or email of support from the Dean, Associate Dean, or Research Centre Director before it can be accepted for review. Generally, this is an email confirming that the Academic Unit has reviewed the project and is supportive for it to proceed. Applicants are asked to upload the approval into ERM in a compulsory section of the application.

8.7 External human research ethics approval

University staff and students listed as investigators on external research projects which have been approved by another appropriately constituted ethics committee need to notify the HREC of their involvement.

For these research projects, a copy of the approved ethics application, copies of all relevant documents (such as Participant/ Information Consent Forms) and the letter of approval from the administering HREC must be submitted to the HREC. A record of the University staff member’s/student’s involvement in the research project will be kept and a memorandum will be sent as acknowledgement, and, where appropriate, approval by the Chair of the TUA HREC.

8.8 Third party involvement in research

Researchers should contact the Research Office for tailored advice regarding the involvement of third parties in research. In many cases, an agreement between the University and the third party must be developed in order to mitigate risks associated with information sharing. Data collected or held by a third party may be subject to relevant national and state legislation.

Researchers sometimes buy access to participants and/or data from third party providers. In the ethics application the researcher should provide:

- a rationale for this approach to sourcing participants,
- evidence that any payments made to participants via this 3rd party are in line with NHMRC’s Payment of Participants in Research Guidelines,
- evidence that the 3rd party has clear ethical policies and processes in place in relation to the collection and management of participants’ data.
9. References


